

## REMARKS

Claims 1-17 are currently pending in the application after entry of the present amendment. New dependent claim 17 has been added. Claim 17 recites "the implantable medical graft according to Claim 1 wherein the plurality of continuous circumferential undulations form annular ridges in the body member." Support for this amendment is found on page 20, lines 10-12, page 22, lines 3-14, and page 23, lines 6-14 in combination with figures 14 and 16.

Applicants thank the Examiner for indicating in the Office Action mailed on 22 August 2007 that the drawings filed on 17 August 2006 have been accepted.

Applicants thank the Examiner for providing an initialed copy of page 4/9 of Form PTO-1449 filed on 30 December 2005 with the Office Action mailed on 22 August 2007.

## CLAIMS

Claims 1-17 are currently pending in the application. Claims 1-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. (WO 01/74274) in combination with various other references. Applicants traverse these rejections and respectfully submit that none of the cited references, either alone or in combination, render the claimed invention obvious. Applicants request that the Examiner reconsider and withdraw these rejections in view of the remarks presented herein.

Applicants note that, in the Office Action dated 2 November 2006, the Examiner rejected all pending claims under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. (WO 01/74274) in view of Hess (WO 92/19310) and in combination with various other references. In the previous Office Action mailed 12 February 2007 and in the current Office Action mailed 22 August 2007, the Examiner has withdrawn Hess as a § 103(a) reference. Nonetheless, the Examiner has maintained all of the same rejections under § 103(a) without relying on Hess. In spite of the Examiner's Response to

Arguments presented in the Office Action mailed 22 August 2007, Applicants submit that these § 103(a) rejections cannot logically be maintained. For example, in the Office Action mailed 2 November 2006, the Examiner rejected claims 1-4 and 13-15 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Hess. After consideration of the Applicants' Response filed on 2 February 2007, the Examiner withdrew Hess as a § 103(a) reference. In the previous and current Office Actions, however, the Examiner has maintained the rejection of claims 1-4 and 13-15 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. alone. If Palmaz et al. in combination with Hess was insufficient to render the claimed invention obvious, the Applicants submit that Palmaz et al. alone cannot render the claimed invention obvious.

The situation is similar for each of the Examiner's rejections in the current Office Action. For each rejection, the Examiner has maintained the same rejection that was presented in Office Action mailed 2 November 2006, except with the withdrawal of Hess as a reference. In each case, this appears equally illogical to the Applicants. If some combination of references, which includes Hess, is insufficient to render claims obvious, it is logically impossible for a subset of the same combination of references, now excluding Hess, to render those same claims obvious.

A. Rejection of Claims 1-4 and 13-15 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al.

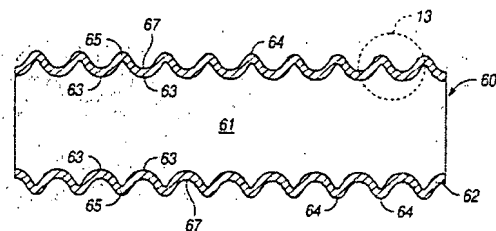
As stated in the MPEP:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (MPEP 706.02(j), underlining added for emphasis.)

Applicants submit that the Examiner's rejection of claims 1-4 and 13-15 is improper because the Examiner has failed to provide a clear suggestion or motivation that would have led one of ordinary skill in the art to modify the prior art in the manner suggested by the Examiner. First, the Applicants note that the Examiner relies on a single prior art reference, Palmaz et al., to support this obviousness rejection. As discussed above, Palmaz et al. in view of Hess was insufficient to render the rejected claims obvious. Palmaz et al. alone is equally insufficient to render the same claims obvious.

The Examiner further asserts that "[i]t would be obvious to one of ordinary skill in the art that the use of a plurality of single elements that each form a circle would result in a medical graft having continuous circumferential undulations." The Applicants respectfully disagree, and, in fact, the Applicants do not understand the Examiner's assertion. The Examiner specifically states that "Palmaz et al. does not disclose the support arranged specifically as having continuous circumferential undulations." And the Examiner fails to point to anything, either within the cited prior art or within the knowledge of one of ordinary skill in the art, to support or explain his assertion.

To illustrate this point more clearly, several figures are reproduced below. The first figure illustrates one embodiment of the Applicants' inventive graft as shown in Figure 12 of the pending application.

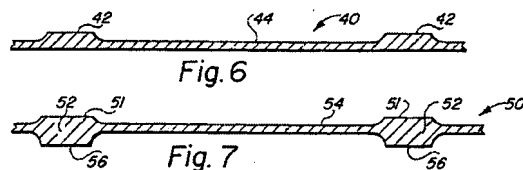


*Fig. 12*

Applicants' graft

As recited in independent claim 1, the claims of the present application are directed to a graft with a “body member having a plurality of continuous circumferential undulations”. Similarly, independent claim 13 recites “a generally cylindrical substrate having a plurality of circumferentially extending continuous undulations with peaks and valleys, patterned along at least a portion of a longitudinal axis of the generally cylindrical substrate.” The application explains that “[t]he graft body member 62 has first and second wall surfaces forming luminal and abluminal surfaces of the graft body member and a plurality of corrugations or pleats 64 forming an undulating pattern of peaks 65 and valleys 67 in wall surfaces of the graft body member.” (Paragraph [0071].)

In contrast, and as acknowledged by the Examiner, the body member described in Palmaz et al. (illustrated in Figures 6 and 7 of Palmaz et al. and reproduced below) does not include a plurality of continuous circumferential undulations.



Palmaz et al. graft

The Examiner has failed to provide an explanation of how Palmaz et al. could render the claimed invention obvious. Palmaz et al. does not provide each element of the claimed invention. Palmaz et al. does not disclose continuous circumferential undulations, nor does Palmaz et al. disclose a “body member having a plurality of continuous circumferential undulations with peaks and valleys, formed in each of the luminal wall and abluminal wall surfaces of the body member.”

In summary, the Examiner has failed to establish a *prima facie* case of obviousness. Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 103(a) rejection of claims 1-4 and 13-15.

B. Rejection of Claims 5, 12, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Van Schie et al.

Claims 5, 12, and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Van Schie et al. (U.S. Patent No. 6,974,471).

As stated in the MPEP:

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). ... If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP § 2143.03, underlining added for emphasis.)

As discussed above, the Examiner has failed to established a *prima facie* case of obviousness with respect to independent claims 1 and 13. Since independent claims 1 and 13 are nonobvious in view of the prior art, all claims depending from independent claims 1 and 13 are also nonobvious. Claims 5 and 12, which depend from independent claim 1, and claim 16, which depends from independent claim 13, are, therefore, also nonobvious.

Also as discussed above, the combination of Palmaz et al., in view of Hess, further in view of Van Schie et al., was insufficient to render rejected claims 5, 12, and 16 obvious. Applicants respectfully submit that they do not understand the Examiner's argument that Palmaz et al., in view of Van Schie et al., without Hess, can render the same claims obvious.

Applicants further note that the suture material referred to in Van Schie et al. is provided in order to create the curved shape of the Van Schie et al. device. Basically, a thread like material is run circumferentially around the Van Schie device in order to impose curvature within the structure. In contrast, the instant claims recite suture openings passing through the wall thickness of the graft that are required for surgical implantation of the graft.

The rejection of claims 5, 12, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Van Schie et al. is improper, and Applicants respectfully request withdrawal of this rejection.

C. Rejection of Claims 6-10 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Van Schie et al., and further in view of Kula et al.

Claims 6-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al., in view of Van Schie et al., and further in view of Kula et al. (U.S. Patent No. 6,325,825). Since the Examiner has failed to establish a *prima facie* case of obviousness with respect to independent claims 1 and 13, all claims depending from independent claims 1 and 13 are also nonobvious. Claims 6-10, which depend from independent claim 1, are, therefore, nonobvious.

The Examiner recognizes that the combination of Palmaz et al. and Van Schie et al. “does not disclose the thickness of the undulating regions as less than that of the non-undulating regions.” The Examiner then asserts that “Kula et al. teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions.” Applicants respectfully disagree. The thicker ends provided in the Kula et al. stent do not correspond to the varying thicknesses of the undulating and non-undulating regions of the claimed graft. As explained in Kula et al.:

“Other modifications at the ends of the stent 10 may include increasing the thickness of wall of the stent 10 and selectively electropolishing. These modifications protect the artery and any plaque from abrasion that may be caused by the stent ends during insertion of the stent 10.”

(Kula et al., col. 4, lines 60-64, underlining added for emphasis.)

Kula provides additional thickness and polishing at the ends of the stent in order to protect vessels from damage caused by the stent ends. This smoothing out of the rough ends of the Kula et al. stent does not correspond to having “the wall thickness of the undulating regions [is] less than the wall thickness of the non-undulating regions” as

recited in claim 6. Even with the combination of four references, the Examiner has not provided each element of the claims as required for a proper 35 U.S.C. § 103(a) rejection.

With respect to claim 7, the Examiner acknowledges that none of the combined references teach or suggest the specific thicknesses recited in claim 7. The Examiner, nonetheless, rejects claim 7 as being obvious. Applicants note that the Examiner has not provided any prior art reference that renders the claimed thicknesses obvious.

With respect to claims 9 and 10, the Examiner acknowledges that none of the references teach or even suggest the “generally cruciform-shaped slot pattern” recited in claim 9 or the “generally Y-shaped slot pattern” recited in claim 10. Nonetheless, the Examiner rejects claims 9 and 10 as being obvious. Applicants once again note that the Examiner has failed to provided any prior art reference that would render claims 9 or 10 obvious. Because the Examiner has made these conclusory statements without citing any prior art reference in support of his conclusion, Applicants interpret the Examiner’s statement to be an official notice. Applicants traverse the Examiner’s official notice and request that the Examiner provide evidentiary support for this official notice.

The rejection of claims 6-10 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al., in view of Van Schie et al., and further in view of Kula et al. is improper, and Applicants respectfully request withdrawal of this rejection.

D. Rejection of Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Banas et al.

Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Banas et al. (U.S. Patent No. 5,749,880). As discussed above, the Examiner has failed to established a *prima facie* case of obviousness with respect to independent claim 1. Since independent claim 1 is nonobvious in view of the prior art, claim 11, which depends from independent claim 1, is also nonobvious.

## CONCLUSION

Applicants respectfully request that the Examiner withdraw the rejections of claims 1-16 based on the remarks presented herein. Applicants thank the Examiner for indicating that the drawing filed on 17 August 2006 have been accepted. Applicants also thank the Examiner for sending the Applicant an initialed copy of page 4/9 of Form PTO-1449 filed on 30 December 2005.

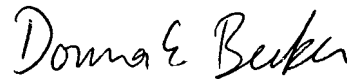
Any amendments made during the prosecution of this application are intended solely to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

This Amendment is being filed submitted a Request for Continued Examination pursuant to 37 C.F.R. § 1.114 and a request for suspension of action for a period of three (3) months pursuant to 37 C.F.R. § 1.103(c). A check in the amount of \$940.00 is enclosed in payment of these fees. The Director is hereby authorized to charge any under payment of fees, or credit any overpayment to Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.



The Applicant's attorney will contact the Examiner to request an interview. The Examiner is also welcome to telephone the undersigned attorney of record if the Examiner believes that there are any outstanding matters capable of resolution by a telephone interview.

Respectfully submitted,



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October 31, 2007

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Docket No. 6006-157